

401 KAR 59:230. New synthesized pharmaceutical product manufacturing operations.

NATURAL RESOURCES AND ENVIRONMENTAL PROTECTION CABINET
Department for Environmental Protection
Division for Air Quality

Relates to: KRS 224.20-100, 224.20-110, 224.20-120

Pursuant to: KRS 13.082, 224.10-100

Necessity and Function: KRS 224.10-100 requires the Department for Natural Resources and Environmental Protection to prescribe regulations for the prevention, abatement, and control of air pollution. This regulation provides for the control of volatile organic compound emissions from new synthesized pharmaceutical product manufacturing operations.

Section 1. Definitions.

As used in this regulation, all terms not defined herein shall have the meaning given to them in 401 KAR 50:010.

- (1) "Affected facility" means operations involved in the manufacture of pharmaceutical products by chemical synthesis, but does not include fermentation, extraction, or formulation and packaging.
- (2) "Extraction" means the manufacture of botanical and biological products by the extraction of organic compounds from vegetative materials or animal tissues.
- (3) "Fermentation" means the production and separation of medicinal chemicals such as antibiotics and vitamins from microorganisms.
- (4) "Formulation and packaging" means the formulation of bulk pharmaceuticals into various dosage forms such as tablets, capsules, injectable solutions, ointments, etc. that can be taken by the patient immediately and in accurate amount.
- (5) "Classification date" means February 4, 1981.
- (6) "kPa" means kilopascals.
- (7) "psi" means pounds per square inch.

Section 2. Applicability.

- (1) This regulation shall apply to:
 - (a) Each affected facility commenced on or after the classification date defined in Section 1 of this regulation and located in a county or portion of a county designated as non attainment for ozone in 401 KAR 51:010, for any classification except marginal; and
 - (b) Each affected facility commenced on or after the effective date of this regulation which is part of a major source located in a county or portion of a county designated attainment or marginal nonattainment for ozone in 401 KAR 51:010.
- (2) Each affected facility commenced on or after the classification date defined in Section 1 of this regulation but prior to the effective date of this regulation which is part of a major source located in a county or portion of a county designated attainment or marginally nonattainment for ozone in 401 KAR 51:010 shall be exempt from this regulation except that control devices and procedures required at the time it commenced shall continue to be operated and maintained.

Section 3. Standard for VOCs.

The owner or operator of an affected facility to which this regulation applies shall install, maintain and operate the control equipment and observe at all times the following operating requirements:

- (1) (a) Each vent from reactors, distillation operations, crystallizers, centrifuges, and vacuum dryers that emit 6.8 kg/day (fifteen (15) lb/day) or more of VOCs shall be equipped with surface condensers or other methods of control which provide emission reductions equivalent to the use of surface condensers which meet the requirements in paragraph (b) of this subsection.
 - (b) If surface condensers are used, the condenser outlet gas temperature shall not exceed the following temperatures (degrees Celsius) when condensing VOCs with the respective minimum vapor pressure (kilopascals). All vapor pressures are measured to twenty (20) degrees Celsius.
 1. Negative twenty-five (25)°C; forty (40) kPa (5.8 psi);
 2. Negative fifteen (15)°C; twenty (20) kPa (2.9 psi);
 3. Zero (0)°C; ten (10) kPa (1.5 psi);
 4. Ten (10)°C: Seven (7) kPa (1.0 psi); and
 5. Twenty-five (25)°C, 3.5 kPa (0.5 psi).
- (2) (a) For air dryers and production equipment exhaust systems that emit 150kg/day (330 lbs/day) or more of VOCs, emission shall be reduced ninety (90) percent.
 - (b) For air dryers and production equipment exhaust systems that emit less than 150 kg/day (330 lbs/day), emissions shall be reduced to fifteen (15) kg/day (thirty-three(33) lbs/day).
- (3) (a) For storage tanks storing VOCs with a vapor pressure greater than twenty-eight (28)kPa(4.1 psi) at twenty (20) °C, one(1) liter of displaced vapor shall be allowed to be released to the atmosphere for every ten (10) liters transferred (i.e., a ninety (90) percent effective vapor balance or equivalent) on truck/rail car delivery to all tanks greater than 7,500 L(2,000 gal) capacity unless the tanks are equipped with floating roofs, vapor recovery systems, or their equivalent. This requirement does not apply to transfer of VOCs from one (1) in-plant location to another.
 - (b) For tanks storing VOCs with a vapor pressure greater than ten (10) kPa (1.5 psi) at twenty (20)°C, the pressure or vacuum conservation vents shall be set at plus or minus 0.2 kPa, unless more effective air pollution control is used.
- (4) All centrifuges containing VOCs, rotary vacuum filters processing liquid containing VOCs and other filters having an exposed liquid surface if the liquid contains VOCs shall be enclosed. This applies to liquids exerting a total VOCs vapor pressure of 3.5 kPa (0.5 psi) or more than twenty (20) °C.
- (5) All in-process tanks containing VOC at any time shall have covers which shall be closed except for short periods when production, sampling, maintenance, or inspection procedures require operator access.
- (6) For liquids containing VOCs, all leaks in which liquid is observed to be running or dripping vessels and equipment (for example: pumps, valves, flanges) shall be repaired within fifteen (15) days. A visual recheck shall be made after repair. If the leak is still present or a new leak

is created by the repair, further maintenance shall be performed until the VOC emission drops below the screening value (observed to be running or dripping). Leaks that cannot be repaired within fifteen (15) days shall be repaired during the next scheduled turnaround. If the cabinet requests it, the owner or operator shall demonstrate to the cabinet's satisfaction why the repairs could not be completed within the initial fifteen (15) day period. If the leak is unable to be brought into compliance, a variance shall be requested and obtained on an individual basis. Case-by-case alternatives approved by the cabinet, but not previously authorized by the U.S.EPA, shall be submitted to the U.S.EPA as a SIP revision. Leak detection or maintenance and repair procedures shall include maintaining a survey log identifying when the leak occurred and reporting every ninety(90) days those leaks not repaired after fifteen (15) days. The operators shall retain the survey log for two (2) years after the inspection is completed.

Section 4. Compliance Timetable.

- (1) Affected facilities which were subject to this regulation as in effect on February 4, 1981, shall have achieved final compliance upon startup.
- (2) The owner or operator of an affected facility that, on or after the effective date of the regulation, becomes subject to this regulation for a reason other than construction, modification, or reconstruction shall be required to complete the following:
 - (a) Submit a final control plan for achieving compliance with this regulation no later than three (3) months after the date the affected facility becomes subject to this regulation.
 - (b) Award the control system contract no later than five (5) months after the date the affected facility becomes subject to this regulation.
 - (c) Initiate on-site construction or installation of emissions control equipment no later than seven (7) months after the date the affected facility becomes subject to this regulation.
 - (d) On-site construction or installation of emission control equipment shall be completed no later than eleven (11) months after the date the affected facility becomes subject to this regulation.
 - (e) Final compliance shall be achieved no later than twelve (12) months after the date the affected facility becomes subject to this regulation.
 - (f) If an affected facility becomes subject to this regulation because it is located in a county previously designated nonurban nonattainment or redesignated in 401 KAR 51:010 after November 15, 1990, final compliance may be extended to May 31, 1995, and the schedule in paragraphs (a) through (d) of this subsection adjusted by the cabinet.

Section 5. Compliance Procedures.

Compliance shall be determined based upon an engineering analysis by the department of control system design, control device efficiency, control system capture efficiency, and other factors that could influence the performance of the system. If requested by the department, performance tests specified by the department shall be conducted to determine the efficiency of the control device.

Section 6. Monitoring Requirements.

If adsorbers, condensers, incinerators or scrubbers are used to achieve compliance with Section 3, the following monitoring devices shall be an integral part of the control device:

- (1) For carbon adsorbers, a monitoring device connected to an alarm device, which indicates carbon bed breakthrough;

- (2) For condensers, a temperature securing device located in the exit gas stream;
- (3) For incinerators, temperature securing devices located in the combustion chamber for thermal incinerators and in the catalyst pre- heat chamber for catalytic incinerators; and
- (4) For scrubbers, flow meters for measuring flow rate of scrubbing medium or pressure drop measuring devices indicating back pressure and pressure drop across the scrubber.

Effective Date: June 24, 1992

	Date Submitted to EPA	Date Approved by EPA	Federal Register
Original Reg	FEB 04, 1981	NOV 24, 1981	46 FR 57486
		MAR 30, 1983	48 FR 13168
1st Revision	OCT 20, 1992	JUN 23, 1994	59 FR 32343